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January 18, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 94P-0036; Food Labeling: *Trans* Fatty
Acids in Nutrition Labeling, Nutrient Content Claims, and
Health Claims; Reopening of the Comment Period

Dear Sir or Madam:

The National Association of Margarine Manufacturers (NAMM) appreciates this opportunity to comment on the Food and Drug Administration's (FDA) proposed rule regarding *trans* fatty acids in nutrition labeling, nutrient content claims, and health claims. Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of the Comment Period, 64 *Fed. Reg.* 75887 (December 5, 2000). Specifically, the agency has reopened the comment period to solicit comment on two specific nutrient content claims, "reduced trans fats" and "reduced saturated and trans fats".

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This Federal Register Notice indicates that FDA received 10 comments on its November 17, 1999 proposal requesting that the final rule on trans fat labeling define the nutrient content claim "reduced trans fat". NAMM submitted one of those ten comments and wishes to reassert its position. A relative claim for "reduced trans fat" should be permitted provided the labeled food has the appropriate percentage reduction in trans fat compared to the reference food and no increase in other relevant nutrients than the reference food. Thus, FDA should allow a "reduced trans fat" claim if there is a 25 percent or more reduction in trans fat and no increase in total fat or saturated fat compared to the reference food.

NAMM recognizes that it is FDA's scientific opinion that trans fat acts similarly to saturated fat on serum cholesterol, however, the agency has clearly stated in its trans fat labeling proposal [64 Fed. Reg. @ 62755] that trans fatty acids are not saturated fats. In its November 17, 1999 proposal, FDA acknowledges that in many processed foods saturated fats and trans fats are used interchangeably to accomplish technical effects and indicated that the agency is trying to prevent the addition of saturated fat to compensate for reduction of trans fat. Adopting the above definition will provide for incentive to lower trans fat levels while not increasing saturated fat levels.

Margarine is one of those categories where this compensation can be used. Historically, the use of higher levels of saturated fats have allowed European margarine producers to produce products with trans fat levels typically lower than found in some U.S. products. Here in the U.S., as well as abroad, new technologies are evolving that may permit a reduction in both saturated and trans fat in margarine products and still deliver the functional characteristics that consumers expect.. As stated in our previous comment, the U.S. margarine industry has on average reduced saturated fat by 37% and trans fat by 59% in its products over the past decade.

NAMM believes the practical outcome everyone seeks for the U.S. population is a reduction in the total consumption of saturated and trans fats. Clearly a reduction in this total is achieved if either saturated or trans fat is reduced provided there is no compensatory increase in the other. To maintain satisfaction levels among some margarine consumers it is necessary to use some saturated fat. While it is now possible to achieve a 25% reduction in trans fat in some margarine, it is technically infeasible to meet consumer expectations for the qualities of all margarine by reducing both trans fat and saturated fat by 25%.

NAMM believes that a "reduced trans fat" content claim based on a 25% reduction in trans fat and no increase in saturated fat is a truthful claim. It is not misleading in that saturated fat has not been increased to compensate for the trans fat reduction, nor by FDA's own standard is trans fat saturated fat. A "reduced trans fat" claim would signal to the consumer that one of the fats targeted for reduction in American diets has been reduced (with no increase in another fat having a similar effect) and is thus more heart-healthy than the reference product, creating a net benefit for the consumer.

While NAMM has no position on the nutrient content claim, "reduced saturated and trans fat", because we do not believe it practically can be met by the vast majority of fat-based products, this claim could be reserved for those few products that can achieve the 25% reduction in both saturated and trans fats while allowing a "reduced trans fat" claim as proposed above to assist consumers in selecting products appropriately reduced in trans fats.

Respectfully submitted,

Richard E. Cristol
President